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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,131	02/01/2002	John C. Russell	6885.US.O1	2508

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EXAMINER	
CEPERLEY, MARY	
ART UNIT	**PAPER NUMBER**
1641	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/062,131	RUSSELL, JOHN C.	
	Examiner	Art Unit	
	Mary (Molly) E. Ceperley	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

a) A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 19, 2007 has been entered.

b) The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

c) Claims 1 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz {US 2003/0013857}.

Schwartz describes a method of attaching a protein to a functionalized solid surface through a hydrazone linkage to form a solid surface-protein complex as described in steps a) through c) of claims 1 and 30 of this application wherein hydrazide-containing macromolecules (e.g. proteins) are immobilized to a functionalized solid support via hydrazone bond formation. See Schwartz, paragraphs [0007], [0016], [0018], [0033], [0134], [0147], [0158] and [0174] – [0181]. Schwartz also describes hydrazone bond formation as being useful for conjugating biomolecules to other biomolecules and to fluorescent dyes (see paragraphs [0031] and [0034] – [0038]). Schwartz further describes the acid cleavage of the hydrazone bond to form products useful for both *in vivo* and *in vitro* applications, the same cleavage involved in the final "disrupting the bond" step of claims 1 and 30 of this application (see paragraphs [0110] – [0012] of Schwartz).

The Schwartz method does not specifically describe a step corresponding to step d) of claims 1 and 30 of this application wherein the protein ("First Macromolecule") is covalently linked to another protein ("Second Macromolecule") before acid cleavage of the protein-reactive surface hydrazone bond.

However, Schwartz does describe the preparation of conjugates of two macromolecules (e.g. proteins) using conventional bifunctional reagents (see Schwartz, paragraphs [0007] – [0016] and [0031]).

Given the generic discussion of Schwartz that biomolecules can be covalently linked to other biomolecules or to solid surfaces via acid cleavable hydrazone linkages, and the discussion that other conventional methods are known for covalently linking biomolecules to one another (Schwartz, paragraph [0012]), it is considered to be well within the skill of the art and therefore obvious, to substitute a protein-protein conjugate {corresponding to the covalently bonded "First Macromolecule" and "Second Macromoolecule" of step d) of claims 1 and 30 of this application} as an analogous reactant in the method of Schwartz which links a solid surface to a macromolecule (e.g. protein) through an acid cleavable hydrazone bond. Note the protein-protein conjugates of Examples 12, 14 and 16 of Schwartz and specifically the enzyme-labeled protein conjugates of Example 20 (HRP-labeled IgG) which correspond to the "Protein1"/"Protein2" conjugates of the figure of this application {see also the alkaline phosphatase labeled antibodies of paragraphs [0087] and [0088] of this application}. The limitation of claim 30 of this application, i.e. the "First Molecule having a molecular weight of at least 2,000 daltons", relates to a molecular weight range conventionally associated with antibodies (a class of proteins).

d) Applicant's arguments filed January 19, 2007 regarding the Schwartz patent have been fully considered. In the paragraph bridging pages 6 and 7 of the Remarks applicant argues that "Schwartz fails to disclose or suggest a multiple-step method" that includes the steps recited in claims 1 and 30 of this application.

It is the examiner's position that given the Schwartz discussion of the applicability of the cleavable hydrazone bond technology to the conjugation of a wide variety of reactants such as solid

surfaces and biomolecules as discussed above, the sequential attachment of a "Second Macromolecule" to a surface-immobilized "First Macromolecule", as claimed, would constitute a routine variation in the sequence of performance of a known set of steps conventionally used to attach biomolecules to each other and/or to solid surfaces via acid cleavable hydrazone bonds as described by Schwartz.

e) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary (Molly) E. Ceperley whose telephone number is (571) 272-0813. The examiner can normally be reached from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le, can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 09, 2007

Mary E. Ceperley

Mary (Molly) E. Ceperley
Primary Examiner
Art Unit 1641